Hamburg, 2015

Reimbursement of Innovative Pharmaceuticals and Medical Devices in Germany
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This document is intended to give a short overview and do not constitute full documentation or consultation of the topic.
Agenda

The German pharmaceutical market

Basic information on German health care system

Reimbursement of innovative drugs (outpatient)

Reimbursement of innovative medical devices (inpatient)

How to find the best reimbursement strategy ?!
The German pharmaceutical market is the 4th largest worldwide

Turnover 2013 in Billion US-Dollar, TOP 10

Source: BPI (2014), based on IMS World Review 2014
It accounts for 23% of the European pharmaceutical market ... and sales are on a high level

Turnover 2013 in %, EU-15

Pharmaceutical expenditure in Germany (in Billion €)

The German health insurers have different instruments of pharmaceutical budget impact control

- **New patented products**
  - Price negotiated with payers (GKV-SV) based on early benefit assessment (AMNOG)

- **„Old“ patented products**
  - Price set by pharmaceutical company
  - Price freeze and mandatory discounts
  - Price negotiated with payers by individual contracts (optional)

- **Generic products (and some „old“ patented)**
  - Reference pricing
  - Price freeze and mandatory discounts

- **OTC products**
  - Price set by pharmaceutical company
  - No reimbursement by SHI (beside exemption list)

* launched before 2011

GKV-SV – National Association of Statutory Health Insurance Funds, SHI – statutory health insurance

Source: Ecker + Ecker GmbH

In inpatient sector there are different mechanisms, see slide “German hospital reimbursement…”
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How to find the best reimbursement strategy ?!
Healthcare in Germany is dominated by a system of statutory health insurers (SHI)

Expenditure on health in Germany 2013 (in %)

- public budget
- care insurance
- pension insurance
- accident insurance
- employer
- private

• PHI 9%
• others 33%
• SHI 58%
• statutory health insurers

PHI – private health insurers
Source: Statistisches Bundesamt (2015)
There is a trend to limit reimbursement of pharmaceuticals and medical devices

Last decades milestones

- **1989**: Reference price system
- **1992**: Doctors budget for prescription
- **2003**: Change in reimbursement of inpatient treatment to per case flat rates (DRGs)
- **2004**: Independent, evidence-based reports e.g. on drugs, non-drug interventions, diagnostic tests and screening tests (IQWiG)
- **2011**: Early benefit assessment (outpatient) – (all new Rx-drugs)
- **2012**: Benefit assessment of medical devices and drugs (inpatient)
- **2013**: Early benefit assessment (outpatient) - (pharmaceuticals in market “Bestandsmarkt”)
- **2014**: End of early benefit assessment (outpatient) - (pharmaceuticals in market “Bestandsmarkt”)
There is a handful of key institutions which define reimbursement for health care in Germany:

G-BA, IQWIG, GKV-Spitzenverband, DIMDI, InEK and PKV-Verband

**The Federal Joint Committee,**

- Decides on coverage and reimbursement of most health care services in Germany (SHI only)
- Decides on early benefit assessment of innovative pharmaceuticals

**Institute for Quality and Efficiency in Health Care,**

- Assesses the medical and economical advantages and disadvantages of pharmaceuticals on (e.g. benefit dossiers) behalf of G-BA

**National Association of SHI Funds,**

- Price negotiations after early benefit assessment
- Decides about pharmaceutical reference prices and maximum amounts

**German Institute of Medical Documentation and Information**

- Cataloguing institute (e.g. ICD and OPS)
- HTA

**InEK**

- Institute for the Hospital Remuneration System
- Implementation, further development and maintenance of the hospital payment system (DRGs)

**Institute for Quality and Efficiency in Health Care,**

- Assesses the medical and economical advantages and disadvantages of pharmaceuticals on (e.g. benefit dossiers) behalf of G-BA

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ICD – international classification of diseases, OPS – German procedure classification, HTA – health technology assessment

Source: Ecker + Ecker GmbH
### Every sector and payer has its own reimbursement logic

Scheme of health care sector, market segments and payment

<table>
<thead>
<tr>
<th>Sector</th>
<th>Statutory health insurance (SHI)</th>
<th>Private health insurance (PHI)</th>
<th>New contractual arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>outpatient</strong></td>
<td>• Fee for service (EBM)</td>
<td>• Fee for service (GOÄ)</td>
<td>• § 130e SGB V “Conditional reimbursement for medical devices”</td>
</tr>
<tr>
<td></td>
<td>• Fee for additional services (GOÄ)</td>
<td></td>
<td>• § 140a SGB V “Integrated care”</td>
</tr>
<tr>
<td><strong>inpatient</strong></td>
<td>• Flat-rate payment system (DRG)</td>
<td>• Flat-rate payment system (DRG)</td>
<td>• § 63 SGB V “Pilot projects”</td>
</tr>
<tr>
<td></td>
<td>• Fee for service (GOÄ)</td>
<td>• Fee for service (GOÄ)</td>
<td>• §116 b SGB V “Ambulant spezialfachärztliche Versorgung”</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Agreement with association of PHI</td>
</tr>
</tbody>
</table>

GOÄ – Gebührenordnung der Ärzte; EBM – Einheitlicher Bewertungsmaßstab
Sources: SGB V and Ecker + Ecker GmbH
The outpatient reimbursement is based on a fee for service system

Outpatient

**SHI: EBM**
- EBM is the Uniform Value Scale with which the SHI pays the medical services
- EBM is regulated by social code book five (SGB V) and the catalogue „EBM“ in its currently valid version
  - contains the catalogue of services, point value per service and needed time per service
  - special chapter for each group of doctors

**PHI: GOÄ**
- In Germany a doctor is not allowed to set his own prices, he has to charge in accordance to the legal medical fee schedule (GOÄ)
- In GOÄ nearly every medical service has a special number of points
- Monetary conversion factor is 0,0582873 € per point

Most prescription are made outpatient so EBM and GOÄ can influence prescription behaviour.

Sources: GKV-Spitzenverband, Kassenärztliche Bundesvereinigung (KBV) and Bundesärztekammer (BÄK)
German hospital reimbursement is based on a flat-rate payment system

Inpatient

- DRG system classifies patients into groups based on diagnosis, age, complications etc. and is mandatory for all hospitals
- For each group a flat-rate payment is defined
- There are additional payments on top of DRGs called ZE (e.g. dialysis and use of certain pharmaceuticals)
- 2015 there are 1105 different DRG codes and 170 ZE
- Reimbursement system is updated every year

Inpatient pharmaceutical pricing is nearly non-regulated but...

- no formal price regulation, but the hospital has to cover its pharmaceutical cost with the fixed reimbursement per case (with few exceptions)
- selling pharmaceuticals to hospitals for inpatient use requires a business case to buyer
- only 10% of all spendings for pharmaceuticals are in inpatient sector, but if a patient has been successfully treated with one medication his willingness to switch is low
### Health insurers are public law cooperations* but competitors

Health insurance companies within SHI – Top 8

<table>
<thead>
<tr>
<th>Name</th>
<th>Insureds</th>
<th>Market share</th>
<th>Pharmaceutical expenditures (total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allgemeine Ortskrankenkassen (AOK)</td>
<td>24.3 mio</td>
<td>39%</td>
<td>11,773 mio €</td>
</tr>
<tr>
<td>Barmer GEK</td>
<td>8.6 mio</td>
<td>14%</td>
<td>4,499 mio €</td>
</tr>
<tr>
<td>Techniker Krankenkasse (TK)</td>
<td>8.6 mio</td>
<td>13%</td>
<td>3,364 mio €</td>
</tr>
<tr>
<td>DAK</td>
<td>6.2 mio</td>
<td>10%</td>
<td>3,562 mio €</td>
</tr>
<tr>
<td>IKK classic</td>
<td>5.4 mio</td>
<td>6%</td>
<td>1,376 mio €</td>
</tr>
<tr>
<td>KKH-Allianz</td>
<td>1.8 mio</td>
<td>3%</td>
<td>885 mio €</td>
</tr>
<tr>
<td>Knappschaft-Bahn-See</td>
<td>1.7 mio</td>
<td>3%</td>
<td>no data</td>
</tr>
<tr>
<td>GWQ Service Plus AG consortium of 45 small insurers</td>
<td>7.2 mio</td>
<td>12%</td>
<td>no data</td>
</tr>
</tbody>
</table>

* non-profit-organisations

Sources: Insurer's company reports 2013, dfg (Dienst für Gesellschaftspolitik), BMG (Bundesministerium für Gesundheit)
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Basic information on German health care system

Reimbursement of innovative drugs (outpatient)

Reimbursement of innovative medical devices (inpatient)

How to find the best reimbursement strategy ?!
Reimbursement of innovative drugs works by early benefit assessment
Legal details of benefit assessment have been defined in 2011

- Mandatory to all new pharmaceuticals (enter German market after 01.01.2011)
- „New pharmaceutical“ is defined as new active substance with existing data exclusivity
- Pharmaceutical company has to prove additional benefit (dossier needed)
- Additional benefit is assessed by IQWiG and proven by G-BA
- Price negotiation depends on the extent of additional benefit proven

Note:
- Abbreviated assessment for orphan drugs
- No assessment of drugs used only inpatient

Sources: SGB V, Verfahrensordnung G-BA and Rahmenvereinbarung zu § 130b Abs. 9 SGB V
Early benefit assessment according to AMNOG follows clear rules

Main steps

- Overall process of benefit assessment and price negotiation takes about 12 months – plus about 12 months of preparation
- Pharmaceutical company can apply for new assessment after 12 months

* If price negotiation fails, the arbitration board makes price decision.
Basis of an early benefit assessment is the manufacturer’s dossier

Manufacturer submit the dossier to the Joint Federal Committee electronically.

- G-BA template for assessment dossier has unfilled 122 pages, filled up to 1000 pages!

- The dossier must be submitted at the time when a drug is first brought into German market and has to contain information on:
  1. authorized application areas,
  2. medical benefit,
  3. medical additional benefit compared to the appropriate comparative therapy,
  4. number of patients and patient groups for which a therapeutically significant additional benefit exists,
  5. therapy costs for the SHI,
  6. requirements for a quality-assured application.

The burden of proof lies completely with the pharmaceutical company.

Sources: § 35a SGB V and Ecker + Ecker GmbH
The two most critical aspects of benefit assessment can be discussed with G-BA in advance

Scientifical advice

<table>
<thead>
<tr>
<th>Slicing of indication:</th>
</tr>
</thead>
<tbody>
<tr>
<td>not formalized, but 5 criteria used so far</td>
</tr>
<tr>
<td>• Treatment schema</td>
</tr>
<tr>
<td>• Naive vs. pretreated patients</td>
</tr>
<tr>
<td>• Mono vs. combination therapy</td>
</tr>
<tr>
<td>• Label comparator</td>
</tr>
<tr>
<td>• Enumeration in section 4.1 SmPC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment comparator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 main criteria to be met</td>
</tr>
<tr>
<td>• Approved in the relevant indication(s)</td>
</tr>
<tr>
<td>• Reimbursable by SHI</td>
</tr>
<tr>
<td>• Adequate therapy according to medical standards</td>
</tr>
<tr>
<td>• Most economic therapy in indication (reference price preferred)</td>
</tr>
</tbody>
</table>
Every decision on additional benefit is made in two dimensions

Dimension of decision making

- **“Large”**
- **“Considerable”**
- **“Minor”**
- **“Additional benefit (not quantified)”**
- **“No additional benefit shown”**
- **“Benefit less than alternative”**

**Extant of additional benefit**

**Strength of additional benefit**

**Quality of Evidence**

- **“Hint”**
- **“Indication”**
- **“Proof”**

Sources:
- Verfahrensordnung G-BA
- Ecker + Ecker GmbH
Effective reimbursement follows benefit assessment

Additional benefit and reimbursement

**Scenario A**
- Additional benefit: No
- Reference-priced group: Yes

Reference price according to § 35 SGB V

**Scenario B**
- Additional benefit: No
- Reference-priced group: No

Reimbursement up to price of appropriate comparator therapy

**Scenario C**
- Additional benefit: Yes
- Reference-priced group: No

Reimbursement higher than price of appropriate comparator therapy

- Additional benefit - Drugs with/without additional benefit in comparison to appropriate comparator therapy
- Reference-priced group - Drugs within or not within a reference-priced group

Sources: Rahmenvereinbarung zu § 130b Abs. 9 SGB V and Ecker + Ecker GmbH
Prices and volumes are defined during negotiation with GKV-Spitzenverband
Details on reimbursement

### Negotiation details

- Price negotiation with GKV-Spitzenverband can not be stopped (opt out only in the first 4 weeks)
- Negotiation is based on dossier, IQWiG assessment and G-BA decision
- Company has to submit the following data: treatment cost, expected volumes for their own product and relevant competitors (not only comparator)
- Company has to submit data on effective prices for their product in other European countries

### Outcome:

- Negotiation is on price and volumes

### Rebate details

#### If no inclusion in FRP group:

- Rebate will be negotiated
- Launch list price (AVP) is unchanged

#### Rebate level will depend on benefit evaluation:

- If additional benefit, then additional rebate negotiations
- If no additional benefit, the net price to sick funds cannot be higher than cost of comparative therapy

#### If no agreement:

- Rebate set by arbitration

### Outcome:

- Discount by rebate (list price is unchanged and rebate is negotiated on list price)
- Manufacturers provide rebate when selling the drug to wholesalers → wholesalers to pharmacies → pharmacies to sick funds
The 7 biggest misunderstandings of benefit assessment in Germany

1. G-BA consultation is similar to NICE
2. Comparative therapy follows EMA
3. Marketing based on rebate contracts can avoid benefit assessment
4. There is free pricing for the first 12 months
5. Additional benefit is proven by regulatory authorities
6. German benefit dossier can be based on global value dossier
7. Orphan drugs are exempted from benefit assessment
**Benefit assessment has wider implications on German pricing, marketing and sales strategy**

<table>
<thead>
<tr>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implication 1</strong></td>
</tr>
<tr>
<td>• Benefit assessment produces a clear statement by G-BA and IQWIG on additional benefit to comparator (available also in English). This statement will actively be used in the marketplace.</td>
</tr>
<tr>
<td><strong>Implication 2</strong></td>
</tr>
<tr>
<td>• G-BA has defined a new health standard for health economic analysis and definition of prices.</td>
</tr>
<tr>
<td><strong>Implication 3</strong></td>
</tr>
<tr>
<td>• In negotiation with SHI – group price and volume is fixed maybe at competitors’ expense.</td>
</tr>
<tr>
<td><strong>Implication 4</strong></td>
</tr>
<tr>
<td>• Prescriber has to navigate between G-BA's decision and existing contracts with SHI.</td>
</tr>
</tbody>
</table>

Source: Ecker + Ecker GmbH
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How to find the best reimbursement strategy ?!
Reimbursement of innovative medical devices works by different applications
Inpatient coverage requires inclusion in an existing code or their modification

Outpatient reimbursement is regulated by different mandated by law catalogues
From 2012 on there is an additional way to get reimbursement of new technologies (§ 137e SGB V)

Benefit assessment for inpatient technologies

Application
- Application from SHI
- Application from manufacturer*

Assessment
- Application of evidence by G-BA

Results
- Evidence sufficient
- Evidence not sufficient, but potential obvious
- Evidence not sufficient

Reimbursement by SHI
- Reimbursement
- Limited reimbursement with obligation for generating new evidence
- No reimbursement

* Potential in broad for new technologies
Sources: G-BA and Ecker + Ecker GmbH
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How to find the best reimbursement strategy ?!
Check reimbursement situation for your innovative products and define strategy

Key questions

<table>
<thead>
<tr>
<th>General Questions</th>
<th>Special Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Check</strong></td>
<td></td>
</tr>
<tr>
<td>• Are there similar products in the market?</td>
<td>Drugs:</td>
</tr>
<tr>
<td>• What is the relevant reimbursement environment?</td>
<td>• Is the product a new one in the sense of early benefit assessment?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Evaluate</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Which evidence is available to support the product value?</td>
<td>Drugs:</td>
</tr>
<tr>
<td>• Which is the adequate study design?</td>
<td>• Has the appropriate comparator therapy already been determined?</td>
</tr>
<tr>
<td>• Where to use the product: in- or outpatient?</td>
<td>• Has this appropriate comparator therapy been considered in your clinical studies?</td>
</tr>
<tr>
<td>• Is the product covered by guidelines?</td>
<td>• What evidence is available for the appropriate comparator therapy?</td>
</tr>
<tr>
<td></td>
<td>• In case of a fix reference pricing: What price to expect?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Define</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Which is the clinical product value (German market)?</td>
<td>Drugs:</td>
</tr>
<tr>
<td>• Which is the economic value to the payer and the patient?</td>
<td>• Which are the international implications?</td>
</tr>
<tr>
<td>• How can medical and economic advantages be quantified for the price negotiations?</td>
<td>Medical Devices:</td>
</tr>
<tr>
<td>• Which is the right activity sequence in the reimbursement process?</td>
<td>• What is the reimbursement gap?</td>
</tr>
<tr>
<td>• How to communicate the value story?</td>
<td></td>
</tr>
</tbody>
</table>

Source: Ecker + Ecker GmbH
Contact us and we will provide you with hands on case stories on successful reimbursement strategies in Germany

<table>
<thead>
<tr>
<th>Name</th>
<th>Main fields of activity and former positions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Thomas Ecker, CEO</td>
<td>Health economist and expert for benefit assessment</td>
</tr>
<tr>
<td></td>
<td>- Universität Bayreuth</td>
</tr>
<tr>
<td></td>
<td>- GCI Management</td>
</tr>
<tr>
<td></td>
<td>- IGES Institut GmbH</td>
</tr>
<tr>
<td></td>
<td>- CEO at EPC HealthCare</td>
</tr>
<tr>
<td>Dr. Christof Ecker, MBA, CEO</td>
<td>Physician and expert in the pharmaceutical market and reference pricing</td>
</tr>
<tr>
<td></td>
<td>- Christian-Albrechts-Universität, Kiel</td>
</tr>
<tr>
<td></td>
<td>- Humboldt Universität, Berlin</td>
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<tr>
<td></td>
<td>- EBS, Oestrich-Winkel</td>
</tr>
<tr>
<td></td>
<td>- Head of IT-development at EPC HealthCare</td>
</tr>
<tr>
<td>Dr. Claudia Pütz, CEO</td>
<td>Mathematician and expert in health insurance</td>
</tr>
<tr>
<td></td>
<td>- AOK Mainz and AOK Berlin</td>
</tr>
<tr>
<td></td>
<td>- Techniker Krankenkasse, Hamburg</td>
</tr>
<tr>
<td></td>
<td>- Accenture Consulting, Kronberg</td>
</tr>
<tr>
<td></td>
<td>- Head of health insurance unit at EPC HealthCare</td>
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</tbody>
</table>
Consulting focus on the pharmaceutical industry, the medical technology and diagnostics companies

> Market Access
> Pricing and Reimbursement
> Benefit assessment
> Reference pricing for pharmaceuticals
> Bids and tenders

Thank you for your attention!

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